NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR VETERINARY USE

3861. Adulteration and misbranding of Wonder mange capsules. U. S. v. John M. Adams. Plea of guilty. Defendant placed on probation for 2 years. (F. D. C. No. 32708. Sample Nos. 21028–L, 21212–L, 29044–L.)

INFORMATION FILED: June 6, 1952, Northern District of Alabama, against John M. Adams, manager of the J. Q. Adams Drug Co., Ashland, Ala.

ALLEGED SHIPMENT: On or about March 15 and April 25, 1951, from the State of Alabama into the States of Texas and Oregon.

LABEL, IN PART: "Wonder Mange Capsules (Canine) Caution:—Not for Human Use Each capsule contains 10 grains Sodium 2 Arsenious Acid."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it purported and was represented to contain 10 grains of a sodium compound of arsenious acid in each capsule, whereas the article did not contain 10 grains of a sodium compound of arsenious acid in each capsule but contained in excess of 10 grains of arsenic trioxide in each capsule.

Misbranding, Section 502 (a), the label statement "Each capsule contains 10 grains Sodium 2 Arsenious Acid" was false and misleading since the article contained in excess of 10 grains of arsenic trioxide in each capsule, and the label statements "Wonder Mange Capsules (Canine)" and "Uses: These capsules may be used in the treatment of All Types of Mange On Dogs" were false and misleading since the statements represented and suggested that the article would be effective in the treatment of all types of mange on dogs, whereas it would not be effective in the treatment of any type of mange on dogs.

Further misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, arsenic trioxide; and, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, "Dogs over 10 pounds body weight should receive one capsule every 3 days until symptoms disappear."

DISPOSITION: October 24, 1952. A plea of guilty having been entered, the court placed the defendant on probation for 2 years.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

3862. Misbranding of Tuinal capsules, Secobarbital Sodium capsules, racemic amphetamine sulfate tablets, pentobarbital sodium capsules, and methyltestosterone linguets. U. S. v. Highland Pharmacies, Inc., and Alec Mendelsohn. Plea of nolo contendere for corporation and plea of guilty for individual. Corporation fined $750; sentence of 90 days in prison imposed against individual. (F. D. C. No. 33714. Sample Nos. 15851–L to 15864–L, incl.)

INFORMATION FILED: October 6, 1952, Western District of Missouri, against Highland Pharmacies, Inc., Kansas City, Mo., and Alec Mendelsohn, manager of the corporation's Store No. 2, at Kansas City, Mo.

NATURE OF CHARGE: On or about July 14, 17, 18, 21, and 22, 1952, while quantities of *Tuinal capsules, Secobarbital Sodium capsules, racemic amphetamine sulfate tablets, pentobarbital sodium capsules,* and *methyltestosterone linguets* were being held for sale at Highland Pharmacies, Inc., Store No. 2, after shipment in interstate commerce, the defendants caused various quantities of the drugs to be dispensed without prescriptions from practitioners licensed by law to administer such drugs. This dispensing was contrary to Section 503 (b) (1) and resulted in the drugs so dispensed being misbranded while held for sale.

DISPOSITION: November 14, 1952. A plea of nolo contendere having been entered on behalf of the corporation and a plea of guilty on behalf of the individual defendant, the court imposed a fine of $750 against the corporation and sentenced the individual to 90 days in prison.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3863. Misbranding of phenobarbital tablets, dextro-amphetamine sulfate tablets, sulfadiazine tablets, and diethylstilbestrol tablets. U. S. v. John E. Stephens (John E. Stephens Drugs), and Andrew J. Collinsworth. Pleas of nolo contendere. John E. Stephens fined $2,000 and Andrew J. Collinsworth $500. (F. D. C. No. 31264. Sample Nos. 31371–L, 31373–L, 31915–L, 31916–L, 31923–L, 31924–L, 31926–L, 31927–L.)

INFORMATION FILED: December 6, 1951, Western District of Tennessee, against John E. Stephens, trading as John E. Stephens Drugs, at Memphis, Tenn., and Andrew J. Collinsworth, pharmacist.

INTERSTATE SHIPMENT: From the States of Pennsylvania and Indiana into the State of Tennessee, of quantities of *phenobarbital tablets, dextro-amphetamine sulfate tablets, sulfadiazine tablets,* and *diethylstilbestrol tablets.*

ALLEGED VIOLATION: On or about February 20 and 23, April 28 and 29, and May 6, 10, and 11, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

John E. Stephens, as owner, was made a defendant in all counts; and, in addition, Andrew J. Collinsworth, the pharmacist, was joined as a defendant in three of the counts involving sales made by him.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged drug failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no warning against use in those pathological con-

*See also No. 3878 (veterinary preparation).